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Pamphlet 40–578

Medical Services

Health Risk Assessment Guidance for the Installation Restoration Program and Formerly Used Defense Sites

Headquarters
Department of the Army
Washington, DC
25 February 91

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SUMMARY of CHANGE

DA PAM 40–578
Health Risk Assessment Guidance for the Installation Restoration Program and Formerly Used Defense Sites

This new pamphlet--

- Prioritizes Army Medical Department (AMEDD) support to the Installation Restoration (IR) and Formerly Used Defense Sites (FUDS)programs (para 1-4a(4)).

- Outlines additional procedures to meet the requirements in AR 200-1 (para 1-5).

- Presents the items which the AMEDD elements will use when reviewing health risk assessments (HRAs) (para 2-lb).

- Lists the program documents and their submission requirements (para 2-2).

- Explains the AMEDD’s methodology for reviewing program documents (para 2-3).

- Presents the sources for determining the cancer risk and hazard index at an investigated site (para 2-4).

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Health Risk Assessment Guidance for the Installation Restoration Program and Formerly Used Defense Sites

By Order of the Secretary of the Army:

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The Adjutant General

History. This UPDATE printing publishes a new pamphlet.

Summary. This pamphlet provides guidance to fulfill responsibilities in AR 200–1 and to prepare and review health risk assessments.

Applicability. This pamphlet applies to the Active Army, Army national Guard, and U.S. Army Reserve.

Proponent and exception authority. Not applicable.

Interim changes. Interim changes to this pamphlet are not official unless they are authenticated by The Adjutant general. Users will destroy interim changes on their expiration dates unless sooner superseded or rescinded.

Suggested Improvements. the proponent agency of this pamphlet is the Office of The surgeon general. Users are invited to send comments and suggested improvements on Department of the Army Form 2028 (Recommended Changes to Publications and Blank Forms) directly to HQDA(SGPS–PSP), 5109 Leesburg Pike, Falls Church, VA 22014–3258.

Distribution. Distribution of this publication is made in accordance with the requirements on DA Form 12–09–E, block number 5142, intended for command level C for Active Army, the ARNG, and USAR.

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Glossary

Unclassified

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Chapter 1
Introduction

1–1. Purpose
This document provides specific guidance to—

a. Army Medical Department (AMEDD) elements in supporting the Installation Restoration (IR) and Formerly Used Defense Sites (FUDS)programs.

b. IR and FUDS program' executing agencies in preparing health risk assessments (HRAs) and obtaining assistance from AMEDD elements.

1–2. References.
Required and related publications are listed in appendix A.

1–3. Explanation of abbreviations and terms.
Abbreviations and special terms used in this pamphlet are explained in the glossary.

1–4. Background
a. The Army established the IR and FUDS programs to clean up old hazardous waste sites on active Army installations and former defense sites.

(1) The IR and FUDS programs are implemented and managed per Federal, State, and local environment laws and regulation, including the Comprehensive Environmental Response, Compensation, and Liability Act as amended by the Superfund Amendments and Reauthorization Act.

(2) Various U.S. Army Corps of Engineers' divisions and districts and field operating activities implement much of the IR and FUDS programs.

(3) Executing agency contractors prepare the vast majority of HRAs and IR and FUDS programs. Due to resource limitations, the AMEDD elements will normally prepare the HRAs only in emergency situations when requested by the Assistant Secretary of the Army(Installations, Logistics, and Environment) (ASA (I,L &E))through either the Deputy Assistant Secretary of the Army(Environment, Safety, and Occupational Health), the Chief of Engineers, or a designated representative.

(4) AMEDD support to the IR and FUDS programs will be prioritized to maintain consistency with the IR program's annual work plan to specific requests of the executing agencies. Within these constraints, sites will be prioritized as follows:

(a) Sites that pose an immediate emergency or a direct threat to human health.

(b) National priority list sites.

(c) Sites that pose an immediate emergency or a direct threat to the environment.

(d) Proposed national priority list sites.

(e) All other sites.

b. The investigation, evaluation, and remediation of abandoned hazardous waste sites is conducted using the guidance in the National Contingency Plan, 55 Federal Register (FR) 8666, and other appropriate State, Department of Defense, and Department of the Army guidance.

(1) The National Contingency Plan implements the U.S.Environmental Protection Agency's (EPA's) Superfund Program.

(2) The four primary phases of a cleanup action are as follows:

(a) Preliminary assessment/site inspection involves the identification of sites on the installation that may pose a threat to human health or to the environment.

(b) Remedial investigation/feasibility study involves an in–depth investigation to determine the nature and extent of the contamination at a site; the evaluation of the need for and proposed extent of remedial action; the evaluation of the remedial action alternatives; and the identification of a preferred alternative, based on the results of feasibility study analyses.

(c) Record of decision documents the remedial action alternative selected through the investigative process required by 55 FR 8666.

(d) Remedial action is any corrective action designed to minimize or eliminate the source of the health and environmental risks according to the feasibility study and the record of decision's selected alternative.

1–5. Specific procedures
AR 200–1, chapters 1and 9, provide the general responsibilities for implementing the IR and FUDS programs. Th fulfill these responsibilities, use the following specific procedures:

a. The ASA (I,L&E) through the Deputy Assistant Secretary of the Army (Environment, Safety and Occupational Health)—

(1) Initiates requests for HRAs in emergency situations to the Surgeon General (TSG).

(2) Assigns relative priority to the AMEDD support (see para 1–4–a(4)).

b. The Surgeon General–

(1) Approves decisions impacting on human health. This includes all HRAs.

(2) Provides overall direction for the AMEDD elements' support.

(3) Develops policy for health aspects of the Installation Restoration Program (IRP).

c. Chief of Engineers–

(1) Initiates requests for HRAs in emergency situations to TSG.

(2) Reimburses the commander, U.S. Army Medical Research and Development Command (USAMRDC) for requested program support.

(3) Performs the following actions through the commander, U.S.-Army Toxic and Hazardous Materials Agency (USATHAMA)–

(a) Provides the central program management of the IRP.

(b)) Seeks input from the AMEDD elements at the initiation of the investigation and evaluation of the health risk of a site.

(c) Develops and manages the U.S. Army's IRP Annual Workplan, which funds the U.S. Army Environmental Hygiene Agency (USAEHA) for IRP support.

(d) Coordinates needed medical research with USAMRDC on a reimbursable basis.

(e) Incorporates the methodology outlined in this pamphlet when preparing scopes of work for contractors.

d. Commander, U.S. Army Health Services Command–

(1) Provides guidance to the U.S. Army Medical Department Activities' and the U.S. Army Medical Centers' preventive medicine services in their IRP support.

(2) Designates the commander, USAEHA to serve as the lead agency for AMEDD support for these programs.

(3) Performs the following actions through the commander, USAEHA:

(a) Provides support and guidance to major Army commands(MACOMs) and executing agencies on health aspects of the IR and FUDS programs. This includes special studies, document reviews, and HRAs.

(b) Provides guidance on the investigation approach for the development of an adequate HRA data base.

(c) Provides guidance on the methodology used to conduct the HRA.

(d) Consolidates and provides comments on the health aspects of the IR and FUDS program document through TSG (HQDA(SGPS–PSP–E), 5109 Leesburg Pike, Falls Church, VA 22041–3258) to the executing agency.

(e) Recommends approval or disapproval to TSG on all HRAs prepared by executing agencies.

(f) Provides information to USATHAMAA pertinent to developing the Annual IRP Workplan and the prioritization of sites for action.

(g) Represents TSG in quarterly IRP status review meetings and Workplan development sessions.

(h) Prepares the HRA in emergency situations when requested by ASA(I,L,&E).

(i) Coordinates with USATHAMA when performing field studies and consultations as requested by MACOMs and executing agencies to ensure proper overall prioritization in the IRP Workplan and to avoid a duplication of effort.

(j) Coordinates with the Agency for Toxic Substances and Disease Registry throughout the remedial investigation of national priority list sites.

e. Commander, MACOM–

(1) Reimburses the commander, USAMRDC for requested program support.

(2) Incorporates the methodology outlined in this pamphlet when preparing scopes of work for contractors.

f. Commander, USAMRDC–

(1) Conducts needed medical research to support the IR and FUDS programs when requested.

(2) Provides a research plan to the Commander, USATHAMA, ATTN:CETHA–IR, Aberdeen Proving Ground (APG), Maryland 21010–5401, in response to mutually agreed requirements, and updates the plan annually in coordination with USATHAMA to ensure that their support agrees with the needs and requirements of the IRP.

(3) Participates in the quarterly progress reviews at USATHAMA.

(4) Advises OTSG on medical research issues associated with the IR and FUDS programs.

(5) Develops environmental criteria for military relevant compounds as required.

g. Commander, U.S. Army Medical Department Activities/U.S.-Army Medical Centers–

(1) Provides health–related technical information to the installation public affairs officer and technical review committee for the installation's IRP sites.

(2) Provides assistance to the installation commander in the investigation and evaluation of the health risk of a site.

h. Commander, installations–

(1) Seeks input from the AMEDD elements at the initiation of the investigation and evaluation of the health risk of a site.

(2) Incorporates the methodology outlined in this pamphlet when preparing scopes of work for contractors.

1–6. Technical Assistance

a. Direct all requests for assistance in relevant program support to the Commander, USAEHA, ATTN: HSHB–ME–S, APG, MD 21010–5422, DSN/AUTOVON 584–3651 or commercial 301–671–3651.

b. This program support includes–

(1) Submitting IR and FUDS program documents for review.

(2) Choosing health risk action levels.

(3) Attending public meetings.

Chapter 2
Preparation and Review of Health Risk Assessments

2–1. Specific guidelines for executing agencies

a. When evaluating the health risk associated with IR and FUDS sites, follow the current EPA 540/1–89/002 and EPA 530/SW–89–031. Also, use other relevant EPA documents and Office of Solid Waste and Emergency Response directives. (See app A.) Discuss variations from this approach with USAEHA. (See para 1–6.)

b. Pay close attention to the following items because the AMEDD elements will focus in these during the review process.

(1) Whenever possible, use actual data, rather than modeling results for current exposure conditions, especially at population receptor sites.

(2) Use site–specific data whenever possible.

(3) Use an appropriate and defensible model for the environmental situation, especially for ground–water and biological systems.

(4) Present a realistic environmental situation. Overly conservative assumptions may not always be necessary nor justified, given the safety margin built into many of the factors used by executing agencies.

(5) Include clear referencing for all sources of assumptions, data, factors, judgments, and opinions.

(6) Provide an adequate quantity and quality of environmental data to support conclusions.

(7) Provide at least one example calculation for each formula or model used in the HRA.

(8) Conduct an adequate and complete ecological assessment as part of the HRA process. (See EPA 540/1–89/001 and EPA 600/3–89/013.)

(9) Present adequate background environmental data to evaluate the contamination at the investigated site.

(10) Cross–reference all input data, especially for tables, citing the reference or previous table from which the data are taken. Make sure enough information is included so that reviewer can reproduce the calculations.

2–2. Submission of all IR and FUDS program documents

Executing agencies will submit seven copies of each of the following document to Commander, USAEHA, ATTN:HSHB–MA–S, APG, MD 21010–5422 for AMEDD review:

a. Preliminary research.

b. Enhanced preliminary assessments.

c. Site inspections.

d. Remedial investigations.

e. Endangerment/Risk assessments.

f. Feasibility studies.

g. Work plans.

h. Statements of Work.

i. Sampling and analysis plans.

2–3. Review methodology of all IR and FUDS program documents

a. General guidance. USAEHA–

(1) Provides input at all stages of the process. This includes not only review of the final program documents but also input into their planning and preparation.

(2) Review and provides input for all documents listed in paragraph 2–2.

(3) Staffs the program–related documents internally and with other AMEDD elements as required.

b. Specific guidance. USAEHA's review will focus on the following critical areas of the IR and FUDS programs' process:

(1) Selection of all appropriate–

(a) Sites for investigation.

(b) Contaminants for potential concern.

(c) Exposure pathways for evaluation.

(d) Receptor populations for evaluation.

(2) Adequacy of the–

(a) Analytical and field data used in the HRA process.

(b) Background data collected to support the HRA.

(3) Selection of the models used in the remedial investigation and in the HRA process.

(4) Methodology used to conduct the HRA.

(5) The accuracy of the representative number of calculations, by recalculation. Care will be taken to address critical pathways likely to drive the cleanup process.

c. Administrative guidance.

(1) USAEHA–

(a) Submits the consolidated AMEDD elements' review comments and the recommended position for approval or disapproval through TSG(HQDA (SGPS–PSP–E), 5109 Leesburg Pike, Falls Church, VA 22014–3258) to the requesting executing agency.

(b) Normally, provides review comments on all documents within 30 days upon receiving them.

(2) Executing agencies should coordinate closely with USAEHA in timeframes and suspense to maintain overall IR and FUDS program prioritization.

2–4. Calculation of cancer risk and hazard indices

a. The Surgeon General adheres to EPA's guidelines for health risk action levels. The executing agencies and contractors will used the integrated risk information system (IRIS) for obtaining the

toxicological information. Attention should be given the specific on–site situation when determining health risk action levels.

b. For further guidance on the hierarchy of sources for this toxicological information use the EPA 540/1–89/002, paragraph 7.4.

(1) These parameters are used to determine the cancer risk and hazard index at an investigated site.

(2) Executing agencies should coordinate all variations from this process with the Commander, USAEHA, ATTN:HSHB–ME–S, APG, MD 21010–5422.

Appendix A
References

Section I
Required Publications

AR 200–1
Environmental Protection and Enhancement. (Cited in summary of change, summary, and para 1–5.)

EPA 530/SW–89–031
RCRA Facility Investigation(RFI) Guidance, Volumes I–IV. OSWER Directive 9502.00–6D. May 1989. (This publication is available as PB 89–200–299 from the U.S. Department of Commerce, National Technical Information Service, 5285 Port Royal Road.Springfield, VA 22161. (703) 487–4650.) (Cited in para 2–1(a).

EPA 540/1–89/001
Risk Assessment Guidance for Superfund, Volume II: Environmental Evaluation Manual, March 1989.(Cited in para 2–1b(8).)

EPA 540/1–891/002
Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual, September 1989. (Cited in para 2–1a and 2–4b.)

EPA 600/3–89/013
Ecological Assessment of Hazardous Waste Sites: A Field and Laboratory Reference. March 1989.(Cited in para 2–lb(8).)

55 FR 8666
National Oil and Hazardous Substances Pollution Contingency Plan. Final Rule, 8 March 1990.(Cited in paras 1–4b and 1–4b(2)(c).)

Section II
Related Publications

53 Federal Register 51962
Proposed Rule, Hazard Ranking System (HRS) for Uncontrolled Hazardous Substance Releases; Appendix A of the National Oil and Hazardous Substances Contingency Plan. 23 December 1988.

53 FR 48830
Proposed Guidelines for Exposure–Related Measurements and Request for Comments, 2 December 1988.

EPA 540/1–86/061
Superfund Risk Assessment Information Directory, OSWER Directive 9285.6 1, November 1986

EPA 540/1–88/001
Superfund Exposure Assessment Manual, OSWER Directive 9285.5–1, April 1988.

EPA 540/2–89/057
Determining Soil Response Action Levels Based on Potential Contaminant Migration to Ground Water: A Compendium of Examples, October 1989.

EPA 540/G–89/004
Guidance for Conducting Remedial Investigations and Feasibility Studies Under the Comprehensive Environmental Response. Compensation, and Liability Act, OSWER Directive 9355.3–01. October 1988

EPA 600/8–87/045
The Risk Assessment Guidelines of 1986, August 1987.

EPA 600/8–89/043
Exposure Factors Handbook.March 1989.

OSWER Directive 9345.0–01
Preliminary Assessment Guidance Fiscal Year 1988, January 1988.

OSWER Directive 9345.1–02
Expanded Site Inspection (ESI). Transitional Guidance for Fiscal Year 1988, October 1987.

Section III
Prescribed Forms
This section contains no entries.

Section IV
Referenced Forms
This section contains no entries.

note 1. U.S Environmental Protection Agency publications are available from U S. Environmental Protection Agency, Office of Research and Development Rm G72, 26 West Martin Luther King Drive, Cincinnati, OH 45268, (513) 569–7562
2. Office of Solid Waste and Emergency Response (OSWER)directives are available from U.S Environmental Protection Agency, ATTN: Superfund Docket information Center, 401 M Street S w., Rm 2424M, Mail Code OS245, Washington, DC 20460, (202) 382–3046.

Glossary

Section I
Abbreviations

AMEDD
Army medical department

APG
Aberdeen Proving Ground

ASA (I, L,&E)
Assistant Secretary of the Army (Installations, Logistics, and Environment)

EPA
Environmental Protection Agency

FR
Federal Register

FUDS
Formerly Used Defense Sites

HRA
health risk assessment

IR
Installation Restoration

IRIS
integrated risk information system

IRP
Installation Restoration Program

MACOMs
major Army commands

TSG
The Surgeon General

USAEHA
U.S. Army Environmental Hygiene Agency

USAMRDC
U.S. Army Medical Research and Development Command

USATHAMA
U.S. Army Toxic and Hazardous Materials Agency

Section II
Terms

AMEDD elements
The Surgeon General, U.S. Army Health Services Command, USAEHA, USABRDL, USAMRDC, and installation medical activity/medical center.

Annual IRP workplan
The IRP workload prioritized for year based on funding constraints.

Contaminants of potential concern
Chemicals that are potentially site–related and whose data are of sufficient quality for use in the quantitative risk assessment.

Hazard index
The sum of more than one hazard quotient for multiple substances and multiple exposure pathways. The hazard index is calculated separately for chronic, subchronic, and shorter–duration exposures.

Hazard quotient
The ratio of a single substance exposure level over a specified period of time (for example, subchronic) to a reference dose for that sub–stance derived from a similar exposure period.

Health risk action level
The cancer rate and hazard index at which there is sufficient health risk to warrant remedial action of some type at an IRP site.

Health risk assessments
The process that defines the adverse health consequences of exposure to toxic chemicals.

Installation restoration program
The Department of Defense's equivalent to the national Superfund Program. It is man–dated by law for the Army to address past and present contamination at active Army installations.

IR and FUDS programs executing agencies
Those organizations that direct the IR and FUDS programs through internal resources and private contractors (such as, USATHAMA, U.S. Army Corps of Engineers, installations, and MACOMs).

Model
A predictive tool used to simulate the movement of contaminants through the environment to receptor sites that are distant from the area of contamination.

Modeling results
The predicted values of the contaminant concentrations that should be present at a specified receptor location, which is distant from the area of contamination.

Population receptor sites
An area containing a specific group of people who may be exposed to the compounds emanating from the area of contamination.

Reference dose
The U.S. Environmental Protection Agency's preferred toxicity value for evaluating noncarcinogenix effects resulting from exposures at Superfund sites.

Section III
Special Abbreviations and Terms
This section contains no entries.

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